

AUG 10 2004

510(k) Summary

Submitter:	SIGNUS Medizintechnik GMBH Rannenbergring 54 Alzennau, Germany D-63755
Contact Person:	Tracy L. Gray, RN, BS RAC Senior Consultant Alquest, Inc. Phone: (763) 588-9873 Fax: (763) 287-3836
Date Prepared:	July 9, 2004
Trade Name:	Curved PEEK Tetris™
Classification Name and Number:	21 CFR 888.3060
Product Code:	MQP
Predicate Device	PEEK Tetris™ cleared under K031757 on 7/30/03.
Device Description:	<p>The Curved PEEK Tetris® Spinal implant is a hollow, slightly curved frame with tapered edges. The upper and lower aspects of the implant are open and the walls feature spikes which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies.</p> <p>The frame is forged from PEEK (PEEK-OPTIMA™ LT1), which is radiolucent, and incorporates small Titanium alloy (TiAl6V4) marker pins so the device can be located within the body. The marker pins meet ASTM F-136 and ISO 5832/3.</p> <p>The Curved PEEK Tetris™ Spinal Implant is available in a variety of sizes ranging from 7mm to 48mm. This enables the surgeon to choose the size suited to the individual pathology and anatomical condition. The Curved PEEK Tetris™ may be implanted individually or in pairs.</p>
Intended Use:	<p>The Curved PEEK Tetris™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.</p> <p>The Curved PEEK Tetris™ may be implanted singularly or in pairs.</p> <p>The supplemental internal fixation systems that may be used with the Curved PEEK Tetris™ Spinal Implant is the same as the PEEK Tetris Spinal Implant and include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).</p>
Statement of Technological Comparison	<p>The subject device have the following similarities:</p> <ul style="list-style-type: none"> • The same indication for use; • The same operating principle; • The same basic design;

	<ul style="list-style-type: none"> • The same materials; • Implanted using the same surgical techniques and equipment; • Used in conjunction with the same types of supplemental internal fixation systems; • The same manufacturing environment; • The same sterilization process; and • The same packaging configurations. <p>In summary, the Curved PEEK Tetris™, as described in this submission is, in the opinion of Signus GMBH, substantially equivalent to the predicate device.</p>
Conclusion:	<p>The Curved PEEK Tetris™ as modified in this submission, is substantially equivalent to the predicate device, PEEK Tetris™ cleared under K031757. This conclusion is based upon the similarities of the devices in terms of functional design, indication for use, principles of operation, materials, and performance characteristics.</p>



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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SIGNUS Medizintechnik GMBH
C/o Ms. Tracy L. Gray, RN, BS, RAC
Senior Consultant
Alquest Incorporated
4050 Olson Memorial Highway, Suite 350
Minneapolis, Minnesota 55422

Re: K041888

Trade/Device Name: Curved PEEK Tetris™ Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: July 11, 2004
Received: July 12, 2004

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

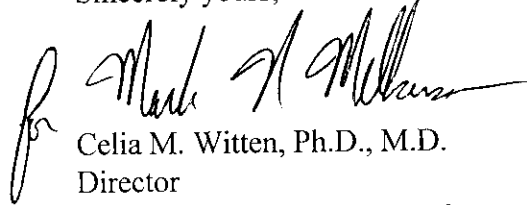
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Tracy L. Gray, RN, BS, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Page

510(k) Number (if known): K041888

Device Name: Curved PEEK Tetris™ Spinal Implant

Indications for Use:

The Curved PEEK Tetris™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.

The Curved PEEK Tetris™ may be implanted singularly or in pairs.

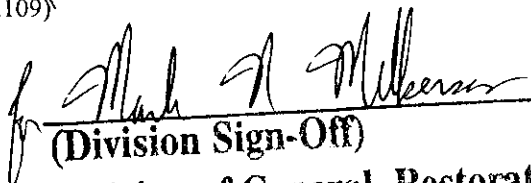
The supplemental internal fixation systems that may be used with the Curved PEEK Tetris™ Spinal Implant is the same as the Curved PEEK Tetris™ Spinal Implant and include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-the-Counter Use _____


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041888